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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

490 7590 06/24/2005

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

COZART, JERMIE E

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,615

Applicant(s)

JOHNSON, MICHAEL W.

Examiner

Jermie Cozart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Appeal Brief

1. In view of the appeal brief filed on April 25, 2005, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 23, 26-30, 32, 35-37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884).

Regarding **claim 23 and 26-30**, Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the

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stent). The tube is formed from metal which is sintered and thereby provided as porous thereby having regions of differing porosity. The stent is cut from the tube after the tube has been formed from sintered metal. A treatment agent (i.e. therapeutic drugs) are disposed on the stent. Yan discloses a stent (12) having been formed according to one embodiment, it is clearly apparent that since Yan discloses forming a stent from a porous tube via laser, it is there safe to surmise that the stent (12) in figure 1 has been formed in the same manner (i.e. laser cutting), wherein stent (12) includes a plurality of serpentine segments extending about the circumference of the stent. As a result of this laser cutting, a plurality of elongate openings are formed whose widths exceed their lengths. *See column 2, lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.*

Regarding **claims 32, 35-37, and 39**, Yan discloses manufacturing a stent, wherein a tube of sintered metal is provided having different predetermined porosities. The tube is cut using a laser thereby forming a plurality of openings in the tube which in turn creates a stent (12) as previously rationalized above having multiple serpentine bands. A treatment agent (i.e. therapeutic agent) is disposed on the stent. Some of the openings are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. The openings which are bounded by at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment include a first side wall and a second side wall extending between and connecting the first and second serpentine segments. The first and second serpentine segments have different physical characteristics (i.e. different porosity). *See column 2,*

lines 7-14 and 39-46; column 3, lines 55-60; column 4, lines 1-11 and 32-65; column 7, lines 30-51; and Figures 1-3 and 6 8 for further clarification.

Yan, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, or a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity; forming multiple serpentine bands such that a first band has a different porosity than a second band.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. Solovay allows the proper amount of therapeutic agents to be delivered to the treatment site. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally

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spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity, in light of the teachings of Solovay, in order to effectively deliver the desired amounts of therapeutic agents to a particular treatment site within the human body.

4. Claims 24, 33, 38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan/Solovay as applied to claims 23, 32, 37, and 40 above, and further in view of Richter (5,807,404).

Yan/Solovay as modified above discloses all of the claimed subject matter except for the following: a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal; the first and second side walls being non-parallel to the longitudinal axis of the stent; or at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal.

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8',9') of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8',9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal. Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine

segment. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. See *column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan/Solovay with a first portion of the tube being made from a first metal and a second portion of the tube, axially spaced from the first portion of the tube being made from a second metal different from the first metal such that the first and second side walls are non-parallel to the longitudinal axis of the stent; and to provide at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal, in light of the teachings of Richter, in order to provide more flexibility at the ends to allow the stent to accommodate the curvature of a vessel in which the stent is implanted.

Response to Arguments

5. Applicant's arguments filed 4/25/05 have been fully considered but they are not persuasive.

Applicant argues that first there is no motivation to make the proposed combination of Yan in view of Solovay, that the combination of the two references would

result in a product having a Yan stent with a Solovay cover, and not a tube with recited regions of different porosity and subsequently cutting a stent from the tube.

In response, the Examiner maintains that Yan teaches first providing a porous tube, and then laser cutting a stent from the tube. The tube has different areas of porosity due to the different sized particles contained in the tube. *See column 2, lines 39-46.* Solovay teaches that a tube can be provided with longitudinally spaced regions of different porosity wherein the porosity is consistent within the regions. Therefore, since Yan already teaches providing a porous tube for making a stent, then Yan is used to only teach that the porosity in the different longitudinally spaced regions can be uniform. Therefore this combination meets the limitations set forth in the claims as mentioned above.

Also, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *See In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 571-272-

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4528. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 571-272-4690. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Allan N. Shoap
Supervisory Patent Examiner
Group 3700



JC
June 16, 2005